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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,817

Applicant(s)

PERRY, BRIAN A.

Examiner

Elizabeth Quan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

1. New corrected drawings are required in this application because they appear to be hand drawn. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.
2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the male portion and its interlocking relationship with the female portion must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 1 is objected to because of the following informalities: "a" between "terminating in" and "male portions" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Neither the specification nor drawings disclose or show a male portion or its interlocking relationship with the female portion. None of the reference characters point out which is the male portion. The specification focuses on the female portion and does not describe how the male and female portions connect. Specifically, on page 3 of the specification, lines 8-11, it states "Embedded in the adapter plate are a series of female portions 18 of the male-female LUER-type connectors to mate with the male portions that are designed into the lower ends of syringes and chromatographic cartridges and columns." It appears that the focus of the invention is the female portions that may be mated with the male portions, but it is not the invention. Furthermore, the description of the embodiment ascribed to FIG. 2 excludes the male portion with the exception of describing the plug as the male LUER-type, which is not the issue at hand. It is confusing that the male portions are recited in the preamble of the claims when it is not part of the invention.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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7. Claim 3 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,832,842 to Limb.

Referring to claim 3, Limb discloses a vacuum manifold (10) for accommodating an adapter and receptacle (12) (see ABSTRACT; FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47). The adapter comprises a plate (16) and plurality of individually removable plugs (84) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47; COL. 3, lines 3-30). The plate (16) has a plurality of through-passages (38) embedded with a female portion (53) of a male-female-type airtight manually operable connector (52,53) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 66 and 67; COL. 2, lines 36-51 and 64-68; COL. 3, lines 1 and 2). Each of the plugs (84) is shaped to mate with a through-passage (56) of one of the female portions (53) to form a substantially airtight closure of the through-passage (56) (see FIG. 8; COL. 3, lines 3-30). The receptacle (12) with an open top has a port (32) for drawing a partial vacuum in the receptacle (12) (FIGS. 1, 2, and 5; COL. 1, lines 44-52 and 62-65). The receptacle (12) has a shoulder (18a) encircling along an inner edge (18) of the open top for supporting the plate (16) across the open top (see FIGS. 1, 2, and 5-8; COL. 1, lines 44-61). The vacuum manifold is designed to produce a vacuum-induced flow through all the through-passages (38) of a multi-well plate, and the adapter renders the vacuum manifold (10) usable for producing vacuum-induced flow through one or a plurality of filtering components (70) terminating in male portions of male-female-type airtight manually operable connectors whose male and female portions are interlocking by sealing o-ring (60) (see ABSTRACT; FIGS. 1-8; COL. 1, lines 44-65; COL. 2, lines 22-68; COL. 3, lines 13, 14, and 20-39). According to Merriam-Webster Collegiate

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Dictionary, interlock is defined as to become locked together or interconnected or united, and interconnected is defined as to connect with one another or to be or become mutually connected. The male and female portions are connected with one another by the sealing o-ring.

The preamble, which recites a vacuum manifold for interchangeably accommodating a multi-well plate and one or a plurality of individual chromatography columns terminating in male portions of one or a plurality of female-type air-tight manually operable connectors who male and female portions are interlocking, has been construed as intended use (see MPEP 2111.02). A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case it does not matter what the manifold or female portion(s) is used for whether the manifold is used for providing a vacuum or the female portion(s) is used to interlock with the male portion(s) such that the chromatography column(s) terminate in male portion(s).

It is noted that the male portion(s) has/have not been positively recited. Therefore, the male portion(s) is/are not accorded patentable weight in the claim. Although the prior art does teach the male portion(s), it is noted that the prior art does not have to teach or fairly suggest limitations that are not positively recited.

Therefore, Limb includes all the limitations in claims 3.

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Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,842 to Limb in view of U.S. Patent No. 6,491,873 to Roberts et al.

Referring to claim 1, Limb discloses a vacuum manifold (10) for accommodating an adapter and receptacle (12) (see ABSTRACT; FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47). The adapter comprises a plate (16) and plurality of individually removable plugs (84) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47; COL. 3, lines 3-30). The plate (16) has a plurality of through-passages (38) embedded with a female portion (53) of a male-female-type airtight manually operable connector (52,53) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 66 and 67; COL. 2, lines 36-51 and 64-68; COL. 3, lines 1 and 2). Each of the plugs (84) is shaped to mate with a through-passage (56) of one of the female portions (53) to form a substantially airtight closure of the through-passage (56) (see FIG. 8; COL.

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3, lines 3-30). The receptacle (12) with an open top has a port (32) for drawing a partial vacuum in the receptacle (12) (FIGS. 1, 2, and 5; COL. 1, lines 44-52 and 62-65). The receptacle (12) has a shoulder (18a) encircling along an inner edge (18) of the open top for supporting the plate (16) across the open top (see FIGS. 1, 2, and 5-8; COL. 1, lines 44-61). The vacuum manifold is designed to produce a vacuum-induced flow through all the through-passages (38) of a multi-well plate, and the adapter renders the vacuum manifold (10) usable for producing vacuum-induced flow through one or a plurality of filtering components (70) terminating in male portions of male-female-type airtight manually operable connectors whose male and female portions are interlocking by sealing o-ring (60) (see ABSTRACT; FIGS. 1-8; COL. 1, lines 44-65; COL. 2, lines 22-68; COL. 3, lines 13, 14, and 20-39). According to Merriam-Webster Collegiate Dictionary, interlock is defined as to become locked together or interconnected or united, and interconnected is defined as to connect with one another or to be or become mutually connected. The male and female portions are connected with one another by the sealing o-ring.

The preamble, which recites a vacuum manifold for interchangeably accommodating a multi-well plate and one or a plurality of individual chromatography columns terminating in male portions of one or a plurality of female-type air-tight manually operable connectors whose male and female portions are interlocking, has been construed as intended use (see MPEP 2111.02). A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the

structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case it does not matter what the manifold or female portion(s) is used for whether the manifold is used for providing a vacuum or the female portion(s) is used to interlock with the male portion(s) such that the chromatography column(s) terminate in male portion(s).

It is noted that the male portion(s) has/have not been positively recited. Therefore, the male portion(s) is/are not accorded patentable weight in the claim. Although the prior art does teach the male portion(s), it is noted that the prior art does not have to teach or fairly suggest limitations that are not positively recited.

Limb does not explicitly disclose an internal shoulder encircling the open top and sized to receive the plate. However, Roberts et al. disclose a receptacle (64) with an internal shoulder encircling the open top sized to receive a plate with a plurality of separation columns (see FIG. 2; COL. 3, lines 52-59). The configuration ensures appropriate alignment and airtight connection between the receptacle and plate to maintain a sufficient vacuum for separation processes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Limb to include an internal shoulder encircling the open top and sized to receive the plate as in Roberts et al. for appropriate alignment and airtight connection between the receptacle and plate for a sufficient vacuum in separation processes.

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10. Alternatively, claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,842 to Limb in view of U.S. Patent No. 5,603,899 to Franciskovich et al. and U.S. Patent No. 6,491,873 to Roberts et al.

Referring to claim 1, Limb discloses a vacuum manifold (10) for accommodating an adapter and receptacle (12) (see ABSTRACT; FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47). The adapter comprises a plate (16) and plurality of individually removable plugs (84) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47; COL. 3, lines 3-30). The plate (16) has a plurality of through-passages (38) embedded with a female portion (53) of a male-female-type airtight manually operable connector (52,53) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 66 and 67; COL. 2, lines 36-51 and 64-68; COL. 3, lines 1 and 2). Each of the plugs (84) is shaped to mate with a through-passage (56) of one of the female portions (53) to form a substantially airtight closure of the through-passage (56) (see FIG. 8; COL. 3, lines 3-30). The receptacle (12) with an open top has a port (32) for drawing a partial vacuum in the receptacle (12) (FIGS. 1, 2, and 5; COL. 1, lines 44-52 and 62-65). The receptacle (12) has a shoulder (18a) encircling along an inner edge (18) of the open top for supporting the plate (16) across the open top (see FIGS. 1, 2, and 5-8; COL. 1, lines 44-61). The vacuum manifold is designed to produce a vacuum-induced flow through all the through-passages (38) of a multi-well plate, and the adapter renders the vacuum manifold (10) usable for producing vacuum-induced flow through one or a plurality of filtering components (70) terminating in male portions of male-female-type airtight manually operable connectors whose male and female portions are interlocking by sealing o-ring (60) (see ABSTRACT; FIGS. 1-8; COL. 1, lines 44-65; COL. 2, lines 22-

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68; COL. 3, lines 13, 14, and 20-39). According to Merriam-Webster Collegiate Dictionary, interlock is defined as to become locked together or interconnected or united, and interconnected is defined as to connect with one another or to be or become mutually connected. The male and female portions are connected with one another by the sealing o-ring.

The preamble, which recites a vacuum manifold for interchangeably accommodating a multi-well plate and one or a plurality of individual chromatography columns terminating in male portions of one or a plurality of female-type air-tight manually operable connectors who male and female portions are interlocking, has been construed as intended use (see MPEP 2111.02). A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case it does not matter what the manifold or female portion(s) is used for whether the manifold is used for providing a vacuum or the female portion(s) is used to interlock with the male portion(s) such that the chromatography column(s) terminate in male portion(s).

It is noted that the male portion(s) has/have not been positively recited. Therefore, the male portion(s) is/are not accorded patentable weight in the claim. Although the prior art does teach the male portion(s), it is noted that the prior art does not have to teach or fairly suggest limitations that are not positively recited.

Limb does not explicitly disclose a chromatographic medium within the male portions. However, it is well known in the art to provide a chromatographic separation medium as evidenced by Franciskovich et al. Franciskovich et al. disclose chromatographic separation medium above the filter fixed within the through-passage of the body of a separation column for entrapping specific constituents of the sample to be separated (see FIG. 5; COL. 3, lines 54-67; COL. 4, lines 1 and 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vacuum manifold of Limb to include a chromatographic separation medium above the filter as in Franciskovich et al. to entrap specific constituents of the sample to be separated.

Limb does not explicitly disclose an internal shoulder encircling the open top and sized to receive the plate. However, Roberts et al. disclose a receptacle (64) with an internal shoulder encircling the open top sized to receive a plate with a plurality of separation columns (see FIG. 2; COL. 3, lines 52-59). The configuration ensures appropriate alignment and airtight connection between the receptacle and plate to maintain a sufficient vacuum for separation processes. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Limb to include an internal shoulder encircling the open top and sized to receive the plate as in Roberts et al. for appropriate alignment and airtight connection between the receptacle and plate for a sufficient vacuum in separation processes.

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10. Alternative, claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,832,842 to Limb in view of U.S. Patent No. 5,603,899 to Franciskovich et al.

Referring to claim 3, Limb discloses a vacuum manifold (10) for accommodating an adapter and receptacle (12) (see ABSTRACT; FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47). The adapter comprises a plate (16) and plurality of individually removable plugs (84) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 44-47; COL. 3, lines 3-30). The plate (16) has a plurality of through-passages (38) embedded with a female portion (53) of a male-female-type airtight manually operable connector (52,53) (see FIGS. 1, 2, 5, 6, and 8; COL. 1, lines 66 and 67; COL. 2, lines 36-51 and 64-68; COL. 3, lines 1 and 2). Each of the plugs (84) is shaped to mate with a through-passage (56) of one of the female portions (53) to form a substantially airtight closure of the through-passage (56) (see FIG. 8; COL. 3, lines 3-30). The receptacle (12) with an open top has a port (32) for drawing a partial vacuum in the receptacle (12) (FIGS. 1, 2, and 5; COL. 1, lines 44-52 and 62-65). The receptacle (12) has a shoulder (18a) encircling along an inner edge (18) of the open top for supporting the plate (16) across the open top (see FIGS. 1, 2, and 5-8; COL. 1, lines 44-61). The vacuum manifold is designed to produce a vacuum-induced flow through all the through-passages (38) of a multi-well plate, and the adapter renders the vacuum manifold (10) usable for producing vacuum-induced flow through one or a plurality of filtering components (70) terminating in male portions of male-female-type airtight manually operable connectors whose male and female portions are interlocking by sealing o-ring (60) (see ABSTRACT; FIGS. 1-8; COL. 1, lines 44-65; COL. 2, lines 22-68; COL. 3, lines 13, 14, and 20-39). According to Merriam-Webster Collegiate

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Dictionary, interlock is defined as to become locked together or interconnected or united, and interconnected is defined as to connect with one another or to be or become mutually connected. The male and female portions are connected with one another by the sealing o-ring.

The preamble, which recites a vacuum manifold for interchangeably accommodating a multi-well plate and one or a plurality of individual chromatography columns terminating in male portions of one or a plurality of female-type air-tight manually operable connectors who male and female portions are interlocking, has been construed as intended use (see MPEP 2111.02). A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case it does not matter what the manifold or female portion(s) is used for whether the manifold is used for providing a vacuum or the female portion(s) is used to interlock with the male portion(s) such that the chromatography column(s) terminate in male portion(s).

It is noted that the male portion(s) has/have not been positively recited. Therefore, the male portion(s) is/are not accorded patentable weight in the claim. Although the prior art does teach the male portion(s), it is noted that the prior art does not have to teach or fairly suggest limitations that are not positively recited.

While Limb does not explicitly disclose a chromatographic medium within the male portions, it is well known in the art to provide a chromatographic separation

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medium as evidenced by Franciskovich et al. Franciskovich et al. disclose chromatographic separation medium above the filter fixed within the through-passage of the body of a separation column for entrapping specific constituents of the sample to be separated (see FIG. 5; COL. 3, lines 54-67; COL. 4, lines 1 and 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the vacuum manifold of Limb to include a chromatographic separation medium above the filter as in Franciskovich et al. to entrap specific constituents of the sample to be separated.

Response to Arguments

11. Applicant's arguments filed 3/19/2003 have been fully considered but they are not persuasive. The term interlocking is defined as to locking together, interconnecting, or uniting by the Merriam-Webster Collegiate Dictionary. Limb discloses the male and female portions are connecting or uniting with each other by means of an o-ring seal. The specification on page 2, line 5 as pointed out by the Applicant does not provide support for interlocking male and female portions. Beginning on line 1 on page 2 of the specification, it states "The invention resides in an adapter plate that is placed on the vacuum manifold opening that would otherwise be occupied by the multi-well plate. The adapter plate has an array of fittings forming through-passages, each of which has the female portion of a Luer-type component or connection embedded in the passage. The connection may be a friction fit or an interlocking connection, or a combination of both." The description of "interlocking" is applied to the relationship between the female portion and the through-passage of the plate not the relationship between the male and

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female portions. Therefore, the interlocking relationship between the male and female portions is new matter.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq
June 10, 2003


Jill Warden
Supervisory Patent Examiner
Technology Center 1700